Complete Summary

GUIDELINE TITLE

Hepatitis B virus.

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Hepatitis B virus. New York (NY): New York State Department of Health; 2008 Jun. 23 p. [49 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Hepatitis B virus. New York (NY): New York State Department of Health; 2004 Sep. 12 p.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Hepatitis B virus (HBV) infection

GUIDELINE CATEGORY

Counseling
Diagnosis
Management
Prevention
Screening
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To develop guidelines for the management of hepatitis B virus infection in human immunodeficiency virus (HIV)-infected patients

TARGET POPULATION

Human immunodeficiency virus (HIV)-infected patients at risk for or co-infected with hepatitis B virus infection

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Screening/Prevention

1. Baseline hepatic function testing
2. Hepatitis B virus (HBV) serologies for all human immunodeficiency virus (HIV)-infected patients, including hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (HBsAb), hepatitis B core antibody (HBcAb) (immunoglobulin G [IgG] or total)
3. Hepatitis A IgG and hepatitis C IgG
4. HBV deoxyribonucleic acid (DNA) test for patients with negative HBsAb, negative HBsAg, and positive HBcAb
5. Counseling patients about behavior modifications including alcohol consumption and transmission
6. HBV vaccination series in HIV-infected patients who are negative for HBsAb (unless they are chronically infected) and revaccination in nonresponders
7. Hepatitis A vaccine (HAV) in HIV-infected patients negative for HAV IgG

Management/Treatment of Acute and Chronic HBV Infection

1. Evaluating the extent of liver disease including HBV-related history, physical examination, laboratory tests (liver function, prothrombin time/international normalized ratio [PT/INR], albumin, and platelet count)

2. Lamivudine for patients with acute HBV accompanied by fulminant liver disease
3. Pegylated interferon alfa-2a for treatment of HBV in HIV-infected patients who decline antiretroviral (ARV) treatment
4. Standard ARV regimen that includes two drugs that are also active against HBV (e.g., tenofovir plus lamivudine or emtricitabine) for patients eligible for both HBV and HIV treatment
5. Monitoring hepatic function in HIV/HBV co-infected patients who discontinue HBV treatment
6. Referring patients with cirrhosis to a hepatologist and for endoscopy
7. Management of patients at risk for hepatocellular carcinoma including screening serum alfa-fetoprotein and annual imaging (computed tomography [CT], magnetic resonance imaging [MRI], or ultrasound) at regular intervals
8. Monitoring treatment response

MAJOR OUTCOMES CONSIDERED

Effectiveness of hepatitis B virus (HBV) vaccination and revaccination

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

AIDS Institute clinical guidelines are developed by distinguished committees of clinicians and others with extensive experience providing care to people with human immunodeficiency virus (HIV) infection. Committees* meet regularly to assess current recommendations and to write and update guidelines in accordance with newly emerging clinical and research developments.

The Committees* rely on evidence to the extent possible in formulating recommendations. When data from randomized clinical trials are not available, Committees rely on developing guidelines based on consensus, balancing the use of new information with sound clinical judgment that results in recommendations that are in the best interest of patients.

*Current committees include:

- Medical Care Criteria Committee
- Committee for the Care of Children and Adolescents with HIV Infection
- Dental Standards of Care Committee
- Mental Health Committee
- Women's Health Committee
- Substance Use Committee
- Physician's Prevention Advisory Committee
- Pharmacy Committee

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

All guidelines developed by the Committee are externally peer reviewed by at least two experts in that particular area of patient care, which ensures depth and quality of the guidelines.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

What's New — June 2008 Update

- Administering the hepatitis B virus (HBV) vaccination series to human immunodeficiency virus (HIV)-infected patients who are negative for hepatitis B surface antigen (HBsAb), unless they are chronically infected.
- Testing for HBsAb between 4 and 12 weeks after vaccination. Nonresponders (HBsAb <10 IU/L) should be revaccinated with another three-dose hepatitis B vaccine series. If a patient's CD4 count is <200 cells/mm^3 or the patient has symptomatic HIV disease, revaccination may be deferred until several months after initiation of antiretroviral (ARV) therapy in an attempt to maximize the antibody response to the vaccine. However, revaccination should not be deferred in pregnant patients or patients who are unlikely to achieve an increased CD4 count.
- Initiating treatment active against HBV when HBV deoxyribonucleic acid (DNA) levels are >2000 IU/mL.
- Initiating ARV therapy when initiating treatment against HBV in HIV/HBV co-infected patients.

Baseline Evaluation, Screening, and Prevention of HIV/HBV Co-Infection

Baseline Hepatic Evaluation

As part of the baseline assessment of HIV-infected patients, clinicians should evaluate liver function, including aspartate aminotransferase (AST) and alanine aminotransferase (ALT).

Hepatitis Screening

As part of the baseline assessment, clinicians should ask HIV-infected patients about their HBV vaccination history and should obtain the following:

- HBV serologies: HBsAg, hepatitis B surface antibody (HBsAb), and hepatitis B core antibody (HBcAb) (immunoglobulin G [IgG] or total)
- Hepatitis A IgG and hepatitis C IgG

Clinicians should obtain an HBV DNA test for patients with negative HBsAb, negative HBsAg, and positive HBcAb to determine whether the patient has occult HBV infection (see Figure 3 in the original guideline document).

Prevention of HIV/HBV Co-Infection

Clinicians should counsel patients about behavior modifications that decrease their risk of acquiring HBV infection through unprotected sexual activity and injection drug use.

<u>Vaccination</u>

Clinicians should administer the HBV vaccination series to HIV-infected patients who are negative for HBsAb, unless they are chronically infected (see Figure 3 in the original guideline document).

Clinicians should test for HBsAb between 4 and 12 weeks after vaccination. Nonresponders (HBsAb <10 IU/L) should be revaccinated with another three-dose hepatitis B vaccine series. If a patient's CD4 count is <200 cells/mm^3 or the patient has symptomatic HIV disease, revaccination may be deferred until several months after initiation of ARV therapy in an attempt to maximize the antibody response to the vaccine. However, revaccination should not be deferred in pregnant patients or patients who are unlikely to achieve an increased CD4 count (see Figure 3 in the original guideline document).

Key Point

Patients who are unlikely to achieve CD4 counts of ≥200 cells/mm^3 after ARV therapy (e.g., patients with hepatitis C virus [HCV] co-infection), as well as HIV-infected pregnant women, are at risk for severe complications resulting from HBV infection.

Key Point

Patient education regarding HBV vaccination is important to ensure awareness of the continued risk for acquiring HBV until adequate surface antibody response is documented.

Hepatitis A Virus (HAV) Co-Vaccination

Clinicians should administer the HAV vaccine to HIV-infected patients who are negative for HAV IgG to prevent concurrent HAV infection.

Evaluation of Patients with Chronic HBV

Clinicians should evaluate the extent of liver disease in patients with chronic hepatitis by:

- Obtaining an HBV-related history
- Performing a physical examination for signs and symptoms of advanced liver disease
- Measuring serial ALT levels, prothrombin time/international normalized ratio (PT/INR), albumin, and platelet count
- Assessing inflammation, fibrosis, HBV replication, and risk of hepatocellular carcinoma (HCC)
- Obtaining hepatitis B envelope antigen (HBeAg), hepatitis B envelope antibody (HBeAb), and HBV DNA quantification (nucleic acid amplification)

If the baseline HBV DNA level is ≤2000 IU/mL in HBeAb-positive patients with elevated ALT, then clinicians should perform serial HBV DNA measurements at least annually.

Key Point

HBeAg negativity can be associated with greater HBV DNA replication and more rapid disease progression in patients carrying mutations in either the precore or the basic core promoter region of the HBV genome.

Counseling for HIV/HBV Co-Infected Patients

Alcohol Consumption

Clinicians should obtain a substance use and alcohol history for HIV/HBV co-infected patients and should refer patients with alcohol abuse or dependence for chemical dependency treatment.

Clinicians should educate HIV/HBV co-infected patients regarding the effects of alcohol on the course of HBV infection. Patients who have other underlying liver disease should be advised to abstain from alcohol.

Transmission

Clinicians should assess for HBV transmission risk behaviors and advise household contacts of HBV carriers to be vaccinated for HBV and to avoid sharing objects that may be contaminated with blood, such as razors or toothbrushes, until their immunity has been confirmed.

Clinicians should encourage all sexually active patients who are positive for HBsAg to use effective barrier protection consistently and correctly, including latex or polyurethane condoms and dental dams, to reduce the risk of transmission of HIV and HBV.

Clinicians should refer active injection drug users for substance use treatment, including opioid substitution therapy. Active injection users who are not ready for treatment should be referred to needle exchange programs.

Treatment of Acute HBV Infection

Patients with acute HBV infection accompanied by fulminant liver disease should receive treatment with lamivudine. Initiation of ARV therapy is not recommended during fulminant hepatitic liver disease.

Clinicians should not treat patients with fulminant hepatitis with adefovir or tenofovir.

Key Point

In an HIV-infected patient with fulminant hepatic failure induced by acute HBV infection, treatment with lamivudine therapy alone is indicated. In patients with less severe hepatic injury from acute HBV infection, and for whom ARV therapy may be indicated, ARV therapy should be deferred until resolution of the acute hepatic insult.

Treatment of Chronic HBV Infection

Clinicians treating HIV/HBV co-infected patients should:

- Initiate treatment active against HBV when HBV DNA levels are >2000 IU/mL
- Consider HBV treatment in patients with detectable HBV DNA ≤2000 IU/mL who also have elevated ALT levels above baseline or fibrosis or inflammation
- Consult with a specialist experienced in the treatment of hepatitis and HIV to discuss treatment decisions, including changes to a patient's existing ARV regimen when HBV treatment is indicated, and to establish a schedule for monitoring

When initiating treatment against HBV in HIV/HBV co-infected patients, clinicians should:

- Initiate ARV therapy
- Use a standard ARV regimen that includes two drugs that are also active against HBV (see Figure 4 in the original guideline document)

Clinicians should avoid discontinuing either HBV or HIV treatment whenever possible and should monitor ALT closely if discontinuation of HBV treatment is unavoidable.

When ARV regimens need to be changed for HIV considerations, the agents active against HBV should be continued whenever possible to avoid risk of reactivation of HBV.

Patients Eligible for Both HBV and HIV Treatment

Clinicians should treat patients who are eligible for both HBV and HIV treatment with an ARV regimen that contains tenofovir plus lamivudine or emtricitabine if such treatment is not contraindicated because of renal insufficiency or fulminant hepatic disease. If the ARV regimen needs to be changed because of HIV resistance to any of these agents, then these agents should still be continued as part of anti-HBV treatment (see Figure 4 in the original guideline document).

Patients with lamivudine or emtricitabine resistance to HBV should receive an alternative ARV regimen with optimal combined anti-HBV activity (see Figure 4 in the original guideline document).

Clinicians should monitor ALT during initiation of or changes to the ARV regimen, especially in patients with cirrhosis.

Key Point

Agents with dual activity against HBV and HIV can simplify treatment regimens because a single agent can be used as part of a regimen to treat both viruses.

Patients with Co-Infection Receiving HBV Treatment but Not HIV Treatment

Clinicians should use pegylated interferon-alfa 2a for the treatment of HBV in HIV-infected patients who decline ARV treatment. No drug other than interferon should be used alone for the treatment of chronic HBV in patients with HIV.

Patients with Co-Infection Eligible for HIV Treatment but Not HBV Treatment

For patients who require HIV treatment and in whom HBV treatment is not indicated, lamivudine or emtricitabine should not be used without tenofovir.

Patients with Cirrhosis

Patients with hepatitis who develop symptomatic cirrhosis should be managed by a clinician experienced in the management of cirrhosis, preferably a hepatologist.

Clinicians should refer HIV/HBV co-infected patients with known cirrhosis for endoscopy every 1 to 2 years to monitor for esophageal varices.

Patients at Risk for Hepatocellular Carcinoma

In patients with chronic HBV who are at higher risk for HCC, clinicians should:

- Screen serum alfa-fetoprotein every 3 to 6 months
- Perform annual imaging with either a triple-phase computed tomography (CT) scan of the abdomen, magnetic resonance imaging (MRI) scan of the abdomen, or hepatic ultrasound, depending on the imaging protocol of the institution
- Perform imaging every 6 months if cirrhosis is present

Monitoring Treatment Response

After initiation of HBV treatment, clinicians should obtain HBV DNA levels and should assess for HBeAg and HBsAg seroconversion every 3 to 6 months.

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for:

- Hepatitis B Virus (HBV) Prevaccination Screening and Vaccination in Human Immunodeficiency Virus (HIV)-Infected Patients
- Initial Treatment for HIV/HBV Co-Infection

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of human immunodeficiency virus (HIV)-infected patients at risk for or co-infected with hepatitis B virus (HBV) infection

POTENTIAL HARMS

- *Interferon-alfa (INF)*. Interferon-alfa should not be used in patients with decompensated cirrhosis. Interferon alfa has numerous side effects and toxicities that should be managed by a clinician experienced with its use.
- *Antiretroviral (ARV) therapy*. HIV/HBV co-infected patients with cirrhosis are at increased risk for a life-threatening hepatitis flare during immune reconstitution after initiation of ARV therapy, particularly when their baseline CD4 count is <200 cells/mm^3. Clinicians should monitor alanine transaminase (ALT) during initiation of or changes to the ARV regimen, especially in patients with cirrhosis.
- *Lamivudine, adefovir, tenofovir*. The ALT levels frequently increase 1 to 2 months after lamivudine is started; this should not prompt discontinuation of the drug. Lamivudine and adefovir should not be used as monotherapy for HBV in HIV-infected patients because HIV resistance will develop rapidly. Clinicians should not treat patients with fulminant hepatitis with adefovir or tenofovir.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The AIDS Institute's Office of the Medical Director directly oversees the development, publication, dissemination and implementation of clinical practice guidelines, in collaboration with The Johns Hopkins University, Division of Infectious Diseases. These guidelines address the medical management of adults, adolescents and children with human immunodeficiency virus (HIV) infection; primary and secondary prevention in medical settings; and include informational brochures for care providers and the public.

Guidelines Dissemination

Guidelines are disseminated to clinicians, support service providers and consumers through mass mailings and numerous AIDS Institute-sponsored educational programs. Distribution methods include the HIV Clinical Resource website, the Clinical Education Initiative (CEI), the AIDS Educational Training Centers (AETC) and the HIV/AIDS Materials Initiative. Printed copies of clinical guidelines are available for order from the New York State Department of Health (NYSDOH) Distribution Center for providers who lack internet access.

Guidelines Implementation

The HIV Clinical Guidelines Program works with other programs in the AIDS Institute to promote adoption of guidelines. Clinicians, for example, are targeted through the CEI and the AETC. The CEI provides tailored educational programming on site for health care providers on important topics in HIV care, including those addressed by the HIV Clinical Guidelines Program. The AETC provides conferences, grand rounds and other programs that cover topics contained in AIDS Institute guidelines.

Support service providers are targeted through the HIV Education and Training initiative which provides training on important HIV topics to non-physician health and human services providers. Education is carried out across the State as well as through video conferencing and audio conferencing.

The HIV Clinical Guidelines Program also works in a coordinated manner with the HIV Quality of Care Program to promote implementation of HIV guidelines in New York State. By developing quality indicators based on the guidelines, the AIDS Institute has created a mechanism for measurement of performance that allows providers and consumers to know to what extent specific guidelines have been implemented.

Finally, best practices booklets are developed through the HIV Clinical Guidelines Program. These contain practical solutions to common problems related to access, delivery or coordination of care, in an effort to ensure that HIV guidelines are implemented and that patients receive the highest level of HIV care possible.

IMPLEMENTATION TOOLS

Clinical Algorithm
Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Hepatitis B virus. New York (NY): New York State Department of Health; 2008 Jun. 23 p. [49 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Mar (revised 2008 Jun)

GUIDELINE DEVELOPER(S)

New York State Department of Health - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

New York State Department of Health

GUIDELINE COMMITTEE

Physicians' Prevention Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Hepatitis B virus. New York (NY): New York State Department of Health; 2004 Sep. 12 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 90 Church Street, New York, NY 10007-2919; Telephone: (212) 268-6108

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Appendix A: hepatitis B virus. New York (NY): New York State Department of Health; 2001 June. Electronic copies: Available in the original guideline document from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

This guideline is available as a Personal Digital Assistant (PDA) download from the New York State Department of Health AIDS Institute Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was prepared by ECRI on January 21, 2004. This NGC summary was updated by ECRI on October 19, 2005. This summary was updated by ECRI Institute on September 2, 2008.

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